Claim 8 (twice amended). A method of cleaning nasal passages comprising; providing a non-steroidal nasal passage cleaning composition consisting of a salt and water base and containing a mucolytic agent, n-acetyl L-cystein, and methyl salicylate, an antiseptic, an analgesic, a decongestant, a moisturizer and a non-steroidal anti-inflammatory, the composition being a sprayable liquid and having a comfortable pH for introduction into the nasal passages; and,

spraying, rinsing or douching the nasal passages with [applying] the liquid composition [to the nasal passages].

REMARKS:

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1 through 9 were in this application, claims 1 and 8 have been amended.

Entry of this amendment is respectfully requested as reducing the issues for appeal and/or placing the application in condition for allowance. Support for the language used in claims 1 and 8 is found on pg. 2, l. 9-12, pg. 3, l. 20-23, and pg. 4, l. 19-23. A new search is not required nor new issues raised as these limitations further clarify the claimed invention, which was claimed as being a liquid for introduction into the nasal passages previously, the terms related to irrigation, spraying, etc. being more specific as to the introduction.

The examiner rejected claims 1, 2 and 4 through 6 as being anticipated by Hughes, et al. To have anticipation, each and every element of the claim must be found in a single prior art reference. W.L. Gore & Assoc., Inc. v. Garlock, Inc., 220 USPQ 303 (Fed. Cir. 1983). Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the art in possession of the invention. In re Spada, 15 USPQ2d 1655 (Fed.

Cir. 1990). An anticipatory reference must be enabling, containing adequate descriptions for practicing the applicant's invention. Akzo N.V. v. Intn'l Trade Comm. 1 U.S.P.Q. 2d 1241 (Fed. Cir.1986).

Hughes does not anticipate each and every element of the applicant's claimed invention, nor provide an enabling disclosure. Hughes describes a cream or ointment applied to the skin containing camphor, menthol and eucalyptus oil, the composition topically applied so that the volatile, aromatic actives are released and thereby the vapors, not the topical composition itself, enters the nasal passages. Hughes describes the first "essential" component of his invention as a volatile aromatic active in col. 3, lines 1-12. This is mixed with a second essential ingredient, a carboxylic acid copolymer that will demulsify on the skin to provide "a continuous oil film on the skin and release of the aromatic actives" col. 3, lines 15-22. As to the oil and water emulsion the examiner referred to, these are described generally as lotions and creams, "well known in the cosmetic art" col. 5, lines 49 through col. 6, line 12. Hughes particularly sought to patent a "topical aromatic releasing composition substantially free from petrolatum", col. 1, lines 9-11, because the compositions having high levels of petrolatum have "an undesirable, greasy and tacky feel" col. 2, lines 10-13.

Neither the examples nor the disclosure in Hughes enables one skilled in the art to produce a nasal passage cleaning composition that is sprayed into the nasal passage. The applicant's invention, as described on page 3 of the specification is distinct "by spraying, rinsing or douching the nasal passages with the inventive composition, the result is dissolution and removal of pollen, smog, dust and other pollutants which cause allergies and decongestion of the nose, opening the sinus orifices for better drainage and a decrease in sinus pressure to relieve sinus headaches." pg. 3, l. 20-23. As an intra-nasal formulation, all of the ingredients in the

inventive cleaning composition are delivered into the nasal passage, to clean and rinse the nasal passage by direct contact.

Hughes only discloses the inhalation of released aromatic actives. It would defy common sense for a person to take an oily skin cream or lotion and force it into the nasal passages. Clearly, the polymers, emollients and other ingredients are designed to coat and adhere to the skin and would deposit in the nasal passages, likely causing more harm than the material sought to be removed by cleaning.

The examiner's comment concerning intended use is misplaced. It is not the intended use, but a property of the formulation itself that defines the claim and is distinguishable from the prior art. The inventive composition is formulated as a sprayable liquid with a comfortable pH for introduction into the nasal passage. The language consisting essentially of is of particular importance as the phrase does not allow inclusion of ingredients which materially alter the basic and novel characteristic of the invention. As described and claimed, the invention is a novel nasal passage cleaning composition for introduction into the nasal passage. Thus, oils, emulsions and other ingredients which prevent use as a nasal passage irrigant are necessarily excluded as they do destroy the basic and novel characteristic of the invention.

For example, the essential carboxylic acid co-polymer, thickeners, silicone oils, etc. which are ingredients in Hughes would not be used in the applicant's invention as these would render it ineffective in cleaning the nasal passages because these likely would deposit in the nasal passages, and themselves require cleaning for removal.

As each and every element of claims 1, 2 and 4 through 6 are not found in Hughes, they are not anticipated by Hughes and the rejection should be withdrawn

Claims 3, 8 and 9 were rejected as being obvious over Hughes in view of Bryce-Smith and further in view Pan et al. It has clearly been established that obviousness cannot be found by combining the teachings of prior art references to produce the claimed invention absent a teaching, suggestion or incentive for doing as the applicant has done. ACS Hospital Systems, Inc. v. Montefiori Hospital, 222 U.S.P.Q. 929 (Fed. Cir. 1984). It is also not within the framework of 35 U.S.C. §103 to pick and choose from the prior art only so much as will support a holding of obviousness to the exclusion of other parts necessary for a full appreciation of what the prior art teaches or suggests, as hindsight is not the test. In re Wesslau 147 U.S.P.Q. 391 (C.C.P.A. 1965). It has been held improper to use the applicant's disclosure as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the results of the claims sought to be invalidated. Orthopedic Equipment Co., Inc. v. United States 217 U.S.P.Q. 193 (Fed. Cir. 1983).

The examiner believes it would be obvious to combine the topical composition of Hughes for releasing aromatic actives with Bryce-Smith, which discloses a treatment for the common cold. As discussed above, Hughes does not teach or suggest a nasal passage cleaning composition for introduction into and irrigating the nasal passages, but rather teaches a topical "less greasy" composition for releasing aromatic actives. Bryce-Smith discloses the use of a zinc sulfate nasal spray as a treatment for the symptoms of the common cold associated with an upper tract infection, particularly congestion and secretion. Examples and figures related to a survey conducted of individuals suffering from the common cold, and the graphs depict differences in the amount of material deposited into preweighed tissues. The tables review the treatment effects in using the zinc spray for treating cold symptoms.

Considering each document as a whole, there is no teaching, suggestion or incentive which would lead one to mix and match components between these patents. The composition of Hughes is described as being particularly formulated for release of aromatic actives which are inhaled whereas the composition of Bryce-Smith is sprayed into the nasal passages for treating symptoms of the common cold. These are distinct delivery systems, and distinct compositions and one skilled in the art would not find a teaching, suggestion or incentive for using aromatic actives in the nasal spray of Bryce-Smith, based on the disclosure of the topical of Hughes. More likely, one may consider using these separately, but there is no teaching that would lead to a combined form. Certainly, as Bryce-Smith issued in 1997, while Hughes issued in 1994, Bryce-Smith was aware of but chose not to teach or suggest that such an incorporation would be useful. Consequently, absent a teaching, suggestion or incentive supporting the combination, the combination is improper.

The further reference to Pan et al does not overcome the deficiency in the combination. Pan et al is related to a lozenge for local administration of medicaments in the upper respiratory tract, specifically defined as being "the larynx, throat and oral pharyngeal area", with the invention related to the controlled formation of a thin bioadhesive film which may bind to the bucoepidial cells which form the surface of the upper respiratory tract. Col. 2, line 47-53. It is notable that the nasal passages are specifically excluded. Considering the document as a whole, there is no question that it relates to cough drops or lozenges which slowly release the contained materials. The patent repeatedly describes the preparation of medicated candy, lozenges, etc. and it is difficult to conceive of a teaching or suggestion for producing a nasal passage clearing composition in Pan. Further, this is yet another delivery system for various materials which is distinct from either the nasal spray of Bryce-Smith or the topical formulation of Hughes. Not

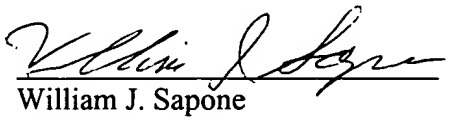
only is there lacking a teaching, suggestion or incentive supporting the combination, one skilled in the art would certainly not look to produce a nasal passage cleaning composition for irrigating the nasal passage by looking to cough drops, lozenges and other orally administered compositions. When each reference is considered as a whole, it is clear that the examiner is picking and choosing from the prior art only so much as will support the opinion of obviousness without a full appreciation of what the prior art teaches or suggests. Thus, the examiner has entered into impermissible hindsight and the rejection for obviousness should be withdrawn.

Clearly, these patents teach away from the applicant's invention. Pan teaches the controlled release delivery of a lozenge that dissolves in the mouth as being an effective treatment whereas Hughes describes a topical skin cream where aromatic actives are released for inhalation and Bryce-Smith teaches yet a different material and method, a nasal spray for delivering zinc for treating the common cold. Nowhere in any of these is there even a suggestion that one should use an intranasal composition for cleaning the nasal passages periodically to remove accumulated contaminants and improve breathing.

A particular advantage of the present invention is that one can achieve nasal passage cleaning with a non-steroidal composition with limited discomfort. Enclosed as exhibit 1 is a result of a survey conducted of users of the applicant's invention. The results show that the inventive composition significantly reduced sinus discomfort, pain, snoring, improved breathing and opening of the nose, with little to no discomfort. Consequently, the applicant's invention is a safe and effective way to clean the nasal passage and to improving breathing, without the side effects of steroidal composition.

Based on the above amendments and remarks reconsideration and removal of the grounds for removal are respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of this application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



William J. Sapone
Registration No. 32,518
Attorney for Applicant(s)

Coleman Sudol Sapone P.C.
714 Colorado Avenue
Bridgeport, CT 06605
Telephone No. (203) 366-3560
Facsimile No. (203) 335-6779

SinusMagic Questionnaire

		%		%		%		%
Sinus discomfort	Better	90.00	Same	3.00	Worse	0.50	N/A	6.50
Pain in Nose	Better	66.90	Same	5.10	Worse	0.43	N/A	27.57
Breathing at Night	Better	80.83	Same	13.10	Worse	0.46	N/A	5.61
Open Nose	Better	91.50	Same	3.00	Worse		N/A	5.50
Snoring	Better	35.50	Same	15.50	Worse		N/A	49.00
Causes Pain in the Nose	None	85.10	Little	14.50	a lot	0.40		
Stinging Sensation	None	74.30	Little	24.30	a lot	1.40		

Note: 214 person with sinus trouble used SinusMagic in this survey.

No placebo control

EXHIBIT A